

|   |                        |                    |            |
|---|------------------------|--------------------|------------|
| <b>INFORMATION DISCLOSURE<br/>STATEMENT BY APPLICANT</b><br>( Not for submission under 37 CFR 1.99) | Application Number     |                    | 10599980   |
|   | Filing Date            |                    | 2007-04-03 |
|   | First Named Inventor   | Roland REINER      |            |
|   | Art Unit               | 1623               |            |
|   | Examiner Name          | Ganapathy KRISHNAN |            |
|   | Attorney Docket Number | 067802-5006-US     |            |

| U.S. PATENTS      |         |               |                        |            |   | Remove   |
|-------------------|---------|---------------|------------------------|------------|---|--|
| Examiner Initial* | Cite No | Patent Number | Kind Code <sup>1</sup> | Issue Date | Name of Patentee or Applicant of cited Document | Pages, Columns, Lines where Relevant Passages or Relevant Figures Appear |
|                   | 1       | 4352883       |                        | 1982-10-05 | Franklin LIM                                    |  |
|                   | 2       | 4424208       |                        | 1984-01-03 | Donald G. WALLACE et al.                        |  |
|                   | 3       | 4663286       |                        | 1987-05-05 | Wen-Ghih TSANG et al.                           |  |
|                   | 4       | 4806355       |                        | 1989-02-21 | Mattheus F.A. GOOSEN et al.                     |  |
|                   | 5       | 5086350       |                        | 1992-02-04 | Sumihiro NISHIHATA                              |  |
|                   | 6       | 5318780       |                        | 1994-06-07 | Tacey X. VIEGAS et al.                          |  |
|                   | 7       | 5633001       |                        | 1997-05-27 | Bengt AGERUP                                    |  |
|                   | 8       | 5800829       |                        | 1998-09-01 | Keith E. DIONNE et al.                          |  |

**INFORMATION DISCLOSURE  
STATEMENT BY APPLICANT**  
( Not for submission under 37 CFR 1.99)

|                        |                    |
|------------------------|--------------------|
| Application Number     | 10599980           |
| Filing Date            | 2007-04-03         |
| First Named Inventor   | Roland REINER      |
| Art Unit               | 1623               |
| Examiner Name          | Ganapathy KRISHNAN |
| Attorney Docket Number | 067802-5008-US     |

|    |         |    |            |                           |  |
|----|---------|----|------------|---------------------------|--|
| 9  | 5916790 |    | 1999-06-29 | Karl C. ENEVOLD           |  |
| 10 | 5922025 |    | 1999-07-13 | William G. HUBBARD        |  |
| 11 | 6214331 | B1 | 2001-04-10 | John W. VANDERHOFF et al. |  |
| 12 | 6264113 | B1 | 2001-06-12 | Douglas W. DINGLER        |  |
| 13 | 6605294 | B2 | 2003-08-12 | Amarpreet S. SAWHNEY      |  |
| 14 | 6642363 | B1 | 2003-11-04 | David J. MOONEY et al.    |  |
| 15 | 7955789 | B2 | 2011-06-07 | Yotaro IZUMI et al.       |  |

If you wish to add additional U.S. Patent citation information please click the Add button.

Add

**U.S.PATENT APPLICATION PUBLICATIONS**

Remove

| Examiner Initial* | Cite No | Publication Number | Kind Code <sup>1</sup> | Publication Date | Name of Patentee or Applicant of cited Document | Pages, Columns, Lines where Relevant Passages or Relevant Figures Appear |
|-------------------|---------|--------------------|------------------------|------------------|---|--|
|                   | 1       | 20020022016        | A1                     | 2002-02-21       | Stephen E. WALSH et al.                         |  |
|                   | 2       | 20020151466        | A1                     | 2002-10-17       | William G. HUBBARD et al.                       |  |

**INFORMATION DISCLOSURE  
STATEMENT BY APPLICANT**  
( Not for submission under 37 CFR 1.99)

|                        |                    |
|------------------------|--------------------|
| Application Number     | 10599980           |
| Filing Date            | 2007-04-03         |
| First Named Inventor   | Roland REINER      |
| Art Unit               | 1623               |
| Examiner Name          | Ganapathy KRISHNAN |
| Attorney Docket Number | 067802-5008-US     |

|   |             |    |            |                              |  |
|---|-------------|----|------------|------------------------------|--|
| 3 | 20050244358 | A1 | 2005-11-03 | Elias Humberto Hermida OCHOA |  |
|---|-------------|----|------------|------------------------------|--|

If you wish to add additional U.S. Published Application citation information please click the Add button. Add

| FOREIGN PATENT DOCUMENTS |         |                                      |                             |                        |                  |  |  | Remove                   |
|--------------------------|---------|--------------------------------------|-----------------------------|------------------------|------------------|--|--|--------------------------|
| Examiner Initial*        | Cite No | Foreign Document Number <sup>3</sup> | Country Code <sup>2</sup> j | Kind Code <sup>4</sup> | Publication Date | Name of Patentee or Applicant of cited Document    | Pages, Columns, Lines where Relevant Passages or Relevant Figures Appear | T <sup>5</sup>           |
|                          | 1       | 0 727 232                            | EP                          | A2                     | 1996-08-21       | Mentor Corporation                                 |  | <input type="checkbox"/> |
|                          | 2       | 1 312 382                            | EP                          | A1                     | 2003-05-21       | Micro Therapeutics, Inc.                           |  | <input type="checkbox"/> |
|                          | 3       | 1991-009119                          | WO                          | A1                     | 1991-06-27       | Trancel Corporation                                |  | <input type="checkbox"/> |
|                          | 4       | 1993-016111                          | WO                          | A1                     | 1993-08-19       | Ulrich ZIMMERMANN et al.                           |  | <input type="checkbox"/> |
|                          | 5       | 1994-021299                          | WO                          | A1                     | 1994-09-29       | Medinvent  |  | <input type="checkbox"/> |
|                          | 6       | 1994-025080                          | WO                          | A1                     | 1994-11-10       | Mass. Institute of Technology & Children's Medical |  | <input type="checkbox"/> |
|                          | 7       | 1996-039464                          | WO                          | A1                     | 1996-12-12       | C.R. Bard, Inc.                                    |  | <input type="checkbox"/> |
|                          | 8       | 1998-023226                          | WO                          | A1                     | 1998-06-04       | Regents of the Univ. of California                 |  | <input type="checkbox"/> |

# INFORMATION DISCLOSURE STATEMENT BY APPLICANT

(Not for submission under 37 CFR 1.99)

|                        |                    |
|------------------------|--------------------|
| Application Number     | 10599980           |
| Filing Date            | 2007-04-03         |
| First Named Inventor   | Roland REINER      |
| Art Unit               | 1623               |
| Examiner Name          | Ganapathy KRISHNAN |
| Attorney Docket Number | 067802-5008-US     |

|    |             |    |    |            |  |                          |
|----|-------------|----|----|------------|--|--------------------------|
| 9  | 1998-052543 | WO | A1 | 1998-11-26 | Massachusetts Institute of Technology et al.   | <input type="checkbox"/> |
| 10 | 2000-009566 | WO | A1 | 2000-02-24 | Ulrich ZIMMERMANN et al.                       | <input type="checkbox"/> |
| 11 | 2002-041928 | WO | A1 | 2002-05-30 | Assistance Publique - Hopitaux de Paris et al. | <input type="checkbox"/> |
| 12 | 2002-076523 | WO | A2 | 2002-10-03 | Soimed Life Systems, Inc.                      | <input type="checkbox"/> |
| 13 | 2003-072155 | WO | A1 | 2003-09-04 | Encelle, Inc. et al.                           | <input type="checkbox"/> |
| 14 | 2003-082359 | WO | A1 | 2003-10-09 | Boston Scientific Limited et al.               | <input type="checkbox"/> |
| 15 | 2004-069294 | WO | A1 | 2004-08-19 | Assistance Publique - Hopitaux de Paris et al. | <input type="checkbox"/> |
| 16 | 2005-105167 | WO | A1 | 2005-11-10 | Cellmed AG et al.                              | <input type="checkbox"/> |

If you wish to add additional Foreign Patent Document citation information please click the Add button [Add](#)

## NON-PATENT LITERATURE DOCUMENTS

[Remove](#)

| Examiner Initials* | Cite No | Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc), date, pages(s), volume-issue number(s), publisher, city and/or country where published.                                 | T <sup>5</sup>           |
|--------------------|---------|---|--------------------------|
|                    | 1       | ATALA et al. - Endoscopic Treatment of Vesicoureteral Reflux with a Chondrocyte-Alginate Suspension - Abstract - Journal of Urology August 1994 - Number 152 (2 Pt 2) - Pages 641-643 - Discussion 644 - 1 page - NCBI Sequence Viewer - PubMed ID 8021988 - National Library of Medicine - USA | <input type="checkbox"/> |

# INFORMATION DISCLOSURE STATEMENT BY APPLICANT

(Not for submission under 37 CFR 1.99)

|                        |                    |
|------------------------|--------------------|
| Application Number     | 10599980           |
| Filing Date            | 2007-04-03         |
| First Named Inventor   | Roland REINER      |
| Art Unit               | 1623               |
| Examiner Name          | Ganapathy KRISHNAN |
| Attorney Docket Number | 067802-5008-US     |

|    |  |                          |
|----|--|--------------------------|
| 2  | BENT et al. - Treatment of Intrinsic Sphincter Deficiency Using Autologous Ear Chondrocytes as a Bulking Agent - Neurology and Uroynamics - 2001 - pages 157-165 - Volume 20 - Number 2 - Wiley-Liss, Inc. - USA   | <input type="checkbox"/> |
| 3  | CLAYTON et al. - The Effect of Capsule Composition on the Biocompatibility of Alginate-Poly-L-Lysine Capsules - Journal of Microencapsulation - April/June 1991 - pages 221-233 - Volume 8 - Number 2 - Taylor & Francis Ltd - United Kingdom  | <input type="checkbox"/> |
| 4  | DRAGET et al. - Alginates from Algae - Polysaccharides and Polyamides in the Food Industry. Properties, Production, and Patents - 2005 - pages 1-30 - WILEY-VCH Verlag GmbH & Co. KGaA - Weinheim - Germany  | <input type="checkbox"/> |
| 5  | ERTESVÄG et al. - Mannuronan C-5-Epimerases and Their Application for in Vitro and in Vivo Design of New Alginates Useful in Biotechnology - Metabolic Engineering - July 1999 - pages 262-269 - Volume 1 - Number 3 - Academic Press - Available online at <a href="http://www.idealibrary.com">http://www.idealibrary.com</a> - USA  | <input type="checkbox"/> |
| 6  | JORK et al. - Biocompatible Alginate from Freshly Collected Laminaria Pallida for Implantation - Journal of Applied Microbiology and Biotechnology - February 2000 - pages 224-229 - Volume 53 - Number 2 - Springer-Verlag - USA and Germany  | <input type="checkbox"/> |
| 7  | LI et al. - Reexamining the Egg-Box Model in Calcium-Alginate Gels with X-Ray Diffraction - Biomacromolecules - February 2007 - pages 464-468 - Volume 8 - Number 2 - American Chemical Society - USA  | <input type="checkbox"/> |
| 8  | MANOJLOVIC et al. - Immobilization of Cells by Electrostatic Droplet Generation: A Model System for Potential Application in Medicine - Original Research - International Journal of Nanomedicine - 2006 - pages 163-171 - Volume 1 - Number 2 - Dove Medical Press Limited - United Kingdom   | <input type="checkbox"/> |
| 9  | MARLER et al. - Soft-Tissue Augmentation with Injectable Alginate and Syngeneic Fibroblasts - Plastic and Reconstructive Surgery - Journal of the American Society of Plastic Surgeons - May 2000 - pages 2049-2058 - Volume 105 - Number 6 - USA  | <input type="checkbox"/> |
| 10 | SPERGER et al. - Analysis of Composition, Molecular Weight, and Water Content Variations in Sodium Alginate Using Solid-State NMR Spectroscopy - Journal of Pharmaceutical Sciences - August 2011 - pages 3441-3452 - Volume 100 - Number 8 - Published online on March 31, 2011 in Wiley Online Library ( <a href="http://www.wileyonlinelibrary.com">wileyonlinelibrary.com</a> ) DOI 10.1002/jps.2252 - Wiley-Liss, Inc. and the American Pharmacists Association - USA | <input type="checkbox"/> |
| 11 | XU et al. - Preparation of the Soft Tissue Bulking Agent Composed of Calcium Alginate Microspheres and Its Resorption in Vito - Chinese Journal of Biomedical Engineering - October 2004 - pages 448-454 - Volume 23 - Number 5 - English Abstract - Page 454 - China  | <input type="checkbox"/> |

If you wish to add additional non-patent literature document citation information please click the Add button **Add**

**INFORMATION DISCLOSURE  
STATEMENT BY APPLICANT**  
( Not for submission under 37 CFR 1.99)

|                        |                    |
|------------------------|--------------------|
| Application Number     | 10599980           |
| Filing Date            | 2007-04-03         |
| First Named Inventor   | Roland REINER      |
| Art Unit               | 1623               |
| Examiner Name          | Ganapathy KRISHNAN |
| Attorney Docket Number | 067802-5008-US     |

**EXAMINER SIGNATURE**

|                    |  |                 |  |
|--------------------|--|-----------------|--|
| Examiner Signature |  | Date Considered |  |
|--------------------|--|-----------------|--|

\*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through a citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

<sup>1</sup> See Kind Codes of USPTO Patent Documents at [www.USPTO.GOV](http://www.USPTO.GOV) or MPEP 901.04. <sup>2</sup> Enter office that issued the document, by the two-letter code (WIPO Standard ST.3). <sup>3</sup> For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. <sup>4</sup> Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST.16 if possible. <sup>5</sup> Applicant is to place a check mark here if English language translation is attached.

**INFORMATION DISCLOSURE  
STATEMENT BY APPLICANT**  
( Not for submission under 37 CFR 1.99)

|                        |                    |
|------------------------|--------------------|
| Application Number     | 10599980           |
| Filing Date            | 2007-04-03         |
| First Named Inventor   | Roland REINER      |
| Art Unit               | 1623               |
| Examiner Name          | Ganapathy KRISHNAN |
| Attorney Docket Number | 067802-5008-US     |

**CERTIFICATION STATEMENT**

Please see 37 CFR 1.97 and 1.98 to make the appropriate selection(s):

- ☐ That each item of information contained in the information disclosure statement was first cited in any communication from a foreign patent office in a counterpart foreign application not more than three months prior to the filing of the information disclosure statement. See 37 CFR 1.97(e)(1).

**OR**

- ☐ That no item of information contained in the information disclosure statement was cited in a communication from a foreign patent office in a counterpart foreign application, and, to the knowledge of the person signing the certification after making reasonable inquiry, no item of information contained in the information disclosure statement was known to any individual designated in 37 CFR 1.56(c) more than three months prior to the filing of the information disclosure statement. See 37 CFR 1.97(e)(2).

- ☐ See attached certification statement.
- ☐ The fee set forth in 37 CFR 1.17 (p) has been submitted herewith.
- ☒ A certification statement is not submitted herewith.

**SIGNATURE**

A signature of the applicant or representative is required in accordance with CFR 1.33, 10.18. Please see CFR 1.4(d) for the form of the signature.

|            |                 |                     |            |
|------------|-----------------|---------------------|------------|
| Signature  | /H. Janice Lee/ | Date (YYYY-MM-DD)   | 2012-02-16 |
| Name/Print | H. Janice Lee   | Registration Number | 64,526     |

This collection of information is required by 37 CFR 1.97 and 1.98. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 1 hour to complete, including gathering, preparing and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. **DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.**

## Privacy Act Statement

The Privacy Act of 1974 (P.L. 93-579) requires that you be given certain information in connection with your submission of the attached form related to a patent application or patent. Accordingly, pursuant to the requirements of the Act, please be advised that: (1) the general authority for the collection of this information is 35 U.S.C. 2(b)(2); (2) furnishing of the information solicited is voluntary; and (3) the principal purpose for which the information is used by the U.S. Patent and Trademark Office is to process and/or examine your submission related to a patent application or patent. If you do not furnish the requested information, the U.S. Patent and Trademark Office may not be able to process and/or examine your submission, which may result in termination of proceedings or abandonment of the application or expiration of the patent.

The information provided by you in this form will be subject to the following routine uses:

1. The information on this form will be treated confidentially to the extent allowed under the Freedom of Information Act (5 U.S.C. 552) and the Privacy Act (5 U.S.C. 552a). Records from this system of records may be disclosed to the Department of Justice to determine whether the Freedom of Information Act requires disclosure of these records.
2. A record from this system of records may be disclosed, as a routine use, in the course of presenting evidence to a court, magistrate, or administrative tribunal, including disclosures to opposing counsel in the course of settlement negotiations.
3. A record in this system of records may be disclosed, as a routine use, to a Member of Congress submitting a request involving an individual, to whom the record pertains, when the individual has requested assistance from the Member with respect to the subject matter of the record.
4. A record in this system of records may be disclosed, as a routine use, to a contractor of the Agency having need for the information in order to perform a contract. Recipients of information shall be required to comply with the requirements of the Privacy Act of 1974, as amended, pursuant to 5 U.S.C. 552a(m).
5. A record related to an International Application filed under the Patent Cooperation Treaty in this system of records may be disclosed, as a routine use, to the International Bureau of the World Intellectual Property Organization, pursuant to the Patent Cooperation Treaty.
6. A record in this system of records may be disclosed, as a routine use, to another federal agency for purposes of National Security review (35 U.S.C. 181) and for review pursuant to the Atomic Energy Act (42 U.S.C. 218(c)).
7. A record from this system of records may be disclosed, as a routine use, to the Administrator, General Services, or his/her designee, during an inspection of records conducted by GSA as part of that agency's responsibility to recommend improvements in records management practices and programs, under authority of 44 U.S.C. 2904 and 2906. Such disclosure shall be made in accordance with the GSA regulations governing inspection of records for this purpose, and any other relevant (i.e., GSA or Commerce) directive. Such disclosure shall not be used to make determinations about individuals.
8. A record from this system of records may be disclosed, as a routine use, to the public after either publication of the application pursuant to 35 U.S.C. 122(b) or issuance of a patent pursuant to 35 U.S.C. 151. Further, a record may be disclosed, subject to the limitations of 37 CFR 1.14, as a routine use, to the public if the record was filed in an application which became abandoned or in which the proceedings were terminated and which application is referenced by either a published application, an application open to public inspections or an issued patent.
9. A record from this system of records may be disclosed, as a routine use, to a Federal, State, or local law enforcement agency, if the USPTO becomes aware of a violation or potential violation of law or regulation.